

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

----- x
SOPHIAS CURE INC. a/k/a SOPHIA'S :
CURE FOUNDATION, :
: Plaintiff, : Case No. 2:16-cv-00865
- against - : : Judge Watson
AVEXIS, INC., et al., : : Magistrate Judge Deavers
Defendants. : :
: :
: :
: :
----- x

**PLAINTIFF'S MEMORANDUM OF LAW IN OPPOSITION TO
DEFENDANTS AVEXIS, INC., SEAN NOLAN AND ARVIND SREEDHARAN'S
MOTION TO DISMISS PLAINTIFF'S FIRST AMENDED COMPLAINT**

John R. Climaco (0011456)
Climaco, Wilcox, Peca, Tarantino &
Garofoli
55 Public Square
Suite 1950
Cleveland, Ohio 44113
Toll Free: (800) 621-1062
Phone: (216) 621-8484
Fax: (216) 771-1632
jrclim@climacolaw.com

Patrick G. Warner (0064604)
Darrin C. Leist (0070533)
Leist Warner LLC
513 East Rich Street, Suite 201
Columbus, Ohio 43215
Telephone: (614) 222.1000
Facsimile: (614) 222-0890
pwarner@leistwarner.com

Salvatore C. Badala (*pro hac vice*)
NAPOLI SHKOLNIK PLLC
360 Lexington Avenue, 11th Floor
New York, New York 10017
Tel: (212) 397-1000
Fax: (646) 843-7603
Email: sbadala@napolilaw.com

TABLE OF CONTENTS

PRELIMINARY STATEMENT.....	1
STATEMENT OF FACTS	2
ARGUMENT	3
I. The First Amended Complaint Sufficiently States a Claim for Tortious Interference.....	3
A. SCF adequately pled that the NCH Defendants breached the Donation Agreement.....	4
1. The Donation Agreement's purpose was to fund the Investigational New Drug Application.....	4
2. The Investigational New Drug Application is a publication.....	5
3. SCF is a "Sponsor" as defined by the Orphan Drug Act.....	7
B. The First Amended Complaint sufficiently alleges that the AveXis Defendants knew the terms of the Donation Agreement and intentionally procured such breach.....	10
1. The AveXis Defendants knew the terms of the Donation Agreement and that their acts would interfere with the Donation Agreement.....	10
2. The AveXis Defendants procured the breach of the Donation Agreement.....	14
C. The First Amended Complaint sufficiently alleges that the AveXis Defendants' actions were unjustified.....	15
CONCLUSION.....	17

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Am. Mut. Share Ins. Corp. v. CUMIS Ins. Soc'y.,</i> No. 08AP-576, 2009 WL 205373 (Ohio Ct. App. Jan. 29, 2009).....	10
<i>DeBoer Structures (U.S.A.) Inc. v. Shaffer Tent And Awning Co.,</i> 233 F. Supp. 2d 934 (S.D. Ohio 2002).....	3
<i>Fred Siegel Co., L.P.A. v. Arter & Hadden,</i> 85 Ohio St.3d 171, (Sup. Ct. Ohio 1999).....	16
<i>Fred Siegel Co., L.P.A v. Arter & Hadden,</i> 85 Ohio St.3d 171, (Sup. Ct. Ohio 1999).....	3
<i>M.J. McPherson Servs., L.L.P. v. Sports Images, Inc.,</i> No. 5:06 CV 465, 2006 WL 2505925, (N.D. Ohio Aug. 28, 2006).....	16
<i>Malibu Media, LLC v. Steiner,</i> 307 F.R.D. 470 (S.D. Ohio 2015)	8
<i>Moorman v. Furbush,</i> No. 1-88-16, 1989 WL 122536 (Ohio Ct. App. 3d Dist. Oct. 10, 1989).....	5
<i>Orme v. Baker,</i> 74 Ohio St. 337 (Sup. Ct. Ohio 1906)	10
<i>Orrenmaa v. CTI Audio, Inc.,</i> 2008-Ohio-4299, ¶ 110 (Ohio Ct. App. 11th Dist. 2008)	10, 12
<i>Reeves v. PharmaJet, Inc.,</i> 846 F. Supp. 2d 791(N.D. Ohio 2012).....	5
<i>Stafford v. Jewelers Mut. Ins. Co.,</i> 554 F. App'x 360, (6th Cir. 2014)	5
<i>Union of Needletrades, Indus. & Textile Employees AFL-CIO v. Am. Capital Strategies, Ltd.,</i> 546 F. Supp. 2d 546 (S.D. Ohio 2008)	14, 15
Statutes	
21 C.F.R. § 312.130(a)	7
21 C.F.R. § 316.3(b)(15)	7
21 U.S.C. § 360cc(a).....	2
Other Authorities	
Black's Law Dictionary (3d Ed. 2006)	6
H.R. REP. NO.99-153, reprinted in 1985 U.S.C.C.A.N. 301	9

Plaintiff Sophias Cure Inc. a/k/a Sophia's Cure Foundation ("SCF") respectfully submits this memorandum of law in opposition to Defendants AveXis, Inc. ("AveXis"), Sean Nolan "Nolan"), and Arvind Sreedharan's ("Sreedharan") (collectively, "AveXis Defendants") motion to dismiss.

PRELIMINARY STATEMENT

Vincent and Catherine Gaynor (the "Gaynors"), founders of Sophias Cure Inc. a/k/a Sophia's Cure Foundation ("SCF"), dedicated their lives to finding a cure for spinal muscular atrophy ("SMA"). SCF was created to assist in funding SMA clinical research and to provide advocacy, awareness, education, and support for families affected by this disease. In 2010, the Gaynors began working with Nationwide Children's Hospital ("NCH"), Nationwide Children's Hospital Foundation (the "Foundation"), and Research Institute at Nationwide Children's Hospital (the "Research Institute") (collectively, the "NCH Defendants") to develop a drug, scAAV9, for SMA. SCF funded the development of scAAV9 based on the promise that SCF would be the Primary Sponsor of scAAV9 before the FDA.

However, as soon as scAAV9 looked like it would be a financial success, the NCH Defendants disregarded its agreement with SCF and partnered with AveXis, Inc. ("AveXis"). AveXis is now listed as the Primary Sponsor of the drug and SCF has nothing to show for its extensive investment of time and money.

Although AveXis and several of its executives—Brian Kaspar (officer and board member), John Carbona ("Carbona") (former CEO), Sean Nolan ("Nolan") (current CEO), and Arvind Sreedharan ("Sreedharan") (VP)—knew about SCF's sponsoring authority and the Donation Agreement, they tortiously interfered with SCF's agreement with NCH Defendants so that AveXis could take over as Sponsor of scAAV9, which it did on October 14, 2015.

The First Amended Complaint sufficiently alleges a claim for tortious interference because SCF adequately pled that: (1) the NCH Defendants breached the Donation Agreement, (2) the AveXis

Defendants knew the terms of the Donation Agreement and intentionally procured such breach, and (3) the AveXis Defendants' actions were unjustified.

For these reasons and those discussed below, SCF respectfully requests that the Court deny the AveXis Defendants' motion to dismiss in its entirety.

STATEMENT OF FACTS

SCF is a non-profit 501(c)(3) public charity that Vincent and Catherine Gaynor (the "Gaynors") formed after their daughter, Sophia, was diagnosed with SMA. (First Amended Complaint ("FAC") ¶ 2.) SCF was created to assist in funding SMA clinical research and to provide advocacy, awareness, education, and support for families affected by this disease. (*Id.*) The Gaynors dedicated their lives to finding a cure for SMA. (*Id.* at ¶ 3.)

In 2010, the Gaynors met Brian Kaspar ("Kaspar"), who is on the faculty at the Research Institute and Chief Scientific Officer, Senior Vice President, Scientific Founder, and a Member of the Board of Directors at AveXis, and began working with him and the NCH Defendants to find a cure for SMA. (*Id.*) In October 2012, SCF entered into a Donation Agreement with the NCH Defendants that recognized SCF as the Primary Sponsor for the Phase 1 study of the Vascular Gene Transfer of the Survival Motor Neuron Gene by scAAV9 ("scAAV9") for SMA Type 1 patients. (*Id.* at ¶ 4.) The Agreement required the NCH Defendants to name SCF as the "primary sponsor" in "all publications." (*Id.*)

In September 2013, the NCH Defendants breached the Donation Agreement when it submitted an Investigational New Drug ("IND") application for scAAV9 to the United States Food and Drug Administration ("FDA") and failed to name SCF as the Sponsor. (*Id.* at ¶ 5.)

On October 3, 2014, the FDA granted orphan drug designation to scAAV9. (*Id.* at ¶ 7.) This confers on the drug's Sponsor the exclusive right to market the orphan drug for seven years for use

in treating the particular disease or condition. *See* 21 U.S.C. § 360cc(a). (*Id.*) SCF never received any benefits for its role as Primary Sponsor of scAAV9.

ARGUMENT

I. The First Amended Complaint Sufficiently States a Claim for Tortious Interference.

“In Ohio, the elements of a claim for tortious interference with contract are: (1) the existence of a contract; (2) the wrongdoer’s knowledge of the contract; (3) the wrongdoer’s intentional procurement of the contract’s breach; (4) a lack of justification; and (5) resulting damages.” *DeBoer Structures (U.S.A.) Inc. v. Shaffer Tent And Awning Co.*, 233 F. Supp. 2d 934, 948–49 (S.D. Ohio 2002) (citing *Fred Siegel Co., LPA v. Arter & Hadden*, 85 Ohio St.3d 171, 176, 707 N.E.2d 853 (Sup. Ct. Ohio 1999)).

The AveXis Defendants contend that the First Amended Complaint (“FAC”) fails to state a claim for tortious interference because SCF fails to plead facts establishing that (1) any contract was breached, (2) the AveXis Defendants knew the terms of the Donation Agreement or intentionally procured such breach, and (3) the AveXis Defendants lacked justification in entering into a license agreement with NCH. (Def’s Br. 7.) The AveXis Defendants are wrong because (1) the Donation Agreement was breached, (FAC ¶¶ 5, 6, 115, 126), (2) the AveXis Defendants knew the terms of the Donation Agreement and intentionally procured such breach, (FAC ¶¶ 9, 67-71, 91-94, 101-04, 106, 124, 125), and (3) the AveXis Defendants lacked justification in entering into the license agreement with NCH because the AveXis Defendants knew the Donation Agreement named SCF the Primary Sponsor prior to executing the license agreement. (FAC ¶¶ 67-71.)¹

¹ The AveXis Defendants adopt and incorporate by reference all arguments set forth in the NCH Defendants’ Memorandum in Support to the extent they are applicable. (Def’s Br. 7 n.6.) SCF also adopts and incorporates all arguments in SCF’s Memorandum in Opposition to the NCH Defendants’ motion to dismiss to the extent they are applicable.

A. SCF adequately pled that the NCH Defendants breached the Donation Agreement.

The AveXis Defendants contend that SCF failed to adequately plead any breach of Contract, because: (1) the Donation Agreement's purpose was to outline a donation pledge, (2) the Investigational New Drug Application ("IND") is not a "publication", and (3) SCF is not a "sponsor" as defined by the Orphan Drug Act. (Def's Br. 7-11.)

1. The Donation Agreement's purpose was to fund the Investigational New Drug Application.

The Donation Agreement's purpose was not to outline a donation pledge. The Donation Agreement states that the purpose of the Donation Agreement is,

[To Fund the] clinical work associated with the Phase 1 Vascular Gene Transfer of [scAAV9] for SMA Type 1 patients, as described in an *Investigational New Drug Application to be submitted to the Food and Drug Administration by the Research Institute at Nationwide Children's Hospital*

(FAC Exh. 2.) (emphasis added). SCF's \$550,000 was used to fund the IND to be submitted by the Research Institute to the FDA.

NCH and the Research Institute are parties to the Donation Agreement pursuant to the alter ego and agency doctrines. (FAC ¶¶ 13-15, 117-121). The AveXis Defendants briefly mention in a footnote that neither the Research Institute nor NCH are parties to the Donation Agreement. (Def's Br. 8 n.8.) However, this issue is fully addressed in SCF's Memorandum in Opposition to the NCH's Defendants Motion to Dismiss at pages 7 – 20. SCF incorporates all arguments in its Memorandum in Opposition with regards to NCH and the Research Institute being parties to the Donation Agreement pursuant to the alter ego and agency doctrines.

The Donation Agreement states, "[i]n *all publications* issued by [the Foundation] that reference [Phase 1 Vascular Gene Transfer of the Survival Motor Neuron Gene by scAAV9 for SMA Type 1 patients], [SCF] shall be recognized by name — The Sophia's Cure Foundation — as the *primary sponsor*]" (FAC Exh. 2.) (emphasis added). The AveXis Defendants again briefly argue in a footnote

that SCF's right to public recognition applies only to the funding of the clinical work, not all activities involving scAAV9. (Def's Br. 8 n. 9.) However, the AveXis Defendants are attempting to modify the Donation Agreement. The public recognition section of the Donation Agreement is not limited to clinical work.

According to the FDA, the IND contains three broad areas: (1) preclinical data to permit an assessment as to whether the product is reasonably safe for initial testing in humans, (2) manufacturing information, and (3) clinical protocols and investigator information.² Clearly, the IND is based on the clinical work associated with the drug. Also, the Donation Agreement defines "Project" and adds "as described in an *Investigational New Drug Application* to be submitted to the Food and Drug Administration by the Research Institute at Nationwide Children's Hospital . . ." (FAC Exh. 2.) Clearly, SCF's right to public recognition applied to the IND.

2. The Investigational New Drug Application is a publication.

The IND is a "publication." The AveXis Defendants offer a definition of "publication" from the Merriam-Webster dictionary. (Def's Br. 9.) However, when defining "publication," courts have routinely referred to Black's Law Dictionary. *See Stafford v. Jewelers Mut. Ins. Co.*, 554 F. App'x 360, 374–75 (6th Cir. 2014) (citing Black's Law Dictionary and the Oxford English Dictionary); *Moorman v. Furbush*, No. 1-88-16, 1989 WL 122536, at *3 (Ohio Ct. App. 3d Dist. Oct. 10, 1989) (citing Black's Law Dictionary, "Publication is defined as: 'To make public; to make known to people in general; ... the act of making the defamatory matter known publicly, of disseminating it, or communicating it to one or more persons[].'") (emphasis added).

² *Investigational New Drug Application*, <http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/investigationalnewdrugindapplication/default.htm> (last accessed Jan. 3, 2017). This Court can take judicial notice of matters of public record, including records of the FDA available on its website. *Reeves v. PharmaJet, Inc.*, 846 F. Supp. 2d 791, 794 (N.D. Ohio 2012).

Black's Law Dictionary defines a "publication" as, "[G]enerally, *the act of declaring or announcing to the public.*"³ Black's Law Dictionary (3d Ed. 2006) (emphasis added). Applying this definition, the IND application submitted by the NCH Defendants is a publication because the NCH Defendants announced and distributed the IND to the public.

First, on April 23, 2014, NCH submitted a registered clinical trial. (FAC ¶ 78.) Clinical trial information conducted under IND applications is published on ClinicalTrials.gov.⁴ (*Id.*) In breach of the Donation Agreement, the clinical trial lists Jerry Mendell (Pediatric Expert at NCH) as the Sponsor and SCF as a "collaborator." The submission should have identified SCF as the Sponsor. *Second*, on October 17, 2013, the NCH Defendants announced to the public, through their website, the status of their submission.⁵ *Third*, again the NCH Defendants announced the IND to the public when on May 20, 2013, Brian Kaspar ("Kaspar"), a faculty member at the Research Institute, emailed the Gaynors and wrote, "IND is coming along very well[.] Please find the audited draft report we are going thru, right now 677 pages. Lots of work going on, but thought you would like to see our packet coming together." (FAC ¶ 55.) *Fourth*, and most alarming, is that the NCH Defendants distributed the IND, in print form to an SCF donor in 2013. (FAC ¶ 59 -61.) The donor was not an employee of NCH.

³ Black's Law Dictionary also contains additional "publication" definitions related to copyright, defamation, and wills and estates.

⁴ "Public information about approved drugs can be found on FDA's Drugs@FDA Web page. Some information about unapproved products, including the results of completed trials (see also clinical trials below), is made available by the sponsors of these trials on the National Institutes for Health's Clinicaltrials.gov Web page." <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm197608.htm> (last visited March 20, 2017).

⁵ *AveXis and BioLife Announce the Research Institute at Nationwide Children's Hospital Received Fast Track Status for Spinal Muscular Atrophy Treatment*, <http://www.nationwidechildrens.org/news-room-articles/avexis-and-biolife-announce-the-research-institute-at-nationwide-childrens-hospital-received-fast-track-status-for-spinal-muscular-atrophy-treatment?contentid=121364>.

The AveXis Defendants argue that the submission of an IND is extremely confidential and cite 21 C.F.R. § 312.130(a). (Def's Br. 9.) However, C.F.R. § 312.130(a) states, “The existence of an investigational new drug application will not be disclosed by FDA *unless it has previously been publicly disclosed or acknowledged.*” (emphasis added). Here, the IND has been publically disclosed and acknowledged by the NCH Defendants. Therefore, the existence of this IND is not confidential.

The IND is clearly a publication because the NCH Defendants made its existence public and disseminated the IND to the public.

3. SCF is a “Sponsor” as defined by the Orphan Drug Act.

SCF is a “Sponsor” as defined by the Orphan Drug Act. The AveXis Defendants contend that nothing in the Donation Agreement gives SCF the right to monetary compensation from any commercialization of scAAV9. However, SCF, knowing the benefits of being a Sponsor of scAAV9, bargained for “sponsor” to be included in the Donation Agreement. (FAC ¶ 44.) SCF knew that if scAAV9 received designation and approval as an orphan drug, SCF, as the drug’s Sponsor, would have the exclusive right to market scAAV9 for seven years for use in treating SMA. *Id.* at ¶ 45. The term “Sponsor” is not casually used by parties involved with IND applications. *Id.* at ¶ 46. Designation and approval of a drug as an orphan drug provides certain benefits to the Sponsor of the drug, including the exclusive right to market the orphan drug for seven years for use in treating the particular disease or condition. *See* 21 U.S.C. § 360cc(a). *Id.* at ¶ 86. As the House Report submitted in connection with the passage of the Orphan Drug Act explained, the *purpose of this seven-year market exclusivity period is to allow the orphan drug’s sponsor “to recoup the cost of development by capturing all revenues from the sale of the drug for the rare disease.”* H.R. REP. NO. 99-153, reprinted in 1985 U.S.C.C.A.N. 301, 303 (emphasis added). *See id.* at ¶ 87.

The AveXis Defendants contend that SCF does not meet the definition of a “Sponsor” pursuant to 21 C.F.R. § 316.3(b)(15). 21 C.F.R. § 316.3(b)(15) defines “Sponsor” as,

[T]he entity that *assumes responsibility* for a clinical or nonclinical investigation of a drug, including the responsibility for compliance with applicable provisions of the act and regulations. A sponsor may be an individual, partnership, *corporation*, or Government agency and may be a manufacturer, scientific institution, or an investigator regularly and lawfully engaged in the investigation of drugs.

Id. (emphasis added). SCF is a *corporation*. On the NYS Department of State, SCF is listed as a “domestic not-for-profit *corporation*.⁶ (See also Compl. ¶¶ 2, 11.) SCF clearly meets the definition of “Sponsor.”

Also, contrary to what the AveXis Defendants would like the Court to believe, SCF did assume responsibility for both the clinical and nonclinical investigation of scAAV9. SCF’s mission is “[t]o assist in funding for clinical research towards finding a cure for [SMA] and to offer support to families affected by this disease by providing advocacy, awareness, education and support.” (*Id.* at ¶ 26.) SCF provided the NCH Defendants with the financial support to develop a cure for SMA. (*Id.* at ¶ 33.) In fact, Vincent Gaynor, co-founder of SCF, attended a teleconference with members of NCH concerning the pre-investigational new drug development clinical trial, and was identified a “Sponsor Attendee.” (*Id.* at ¶ 37.) SCF was again referred to as Sponsor when Adam Bevan (NCH) emailed a member of BioReliance, a firm hired to perform toxicology and biodistribution studies for the parties: “[O]ur sponsors are curious when we might get started with the study.” Subsequently, the email was forwarded to Gaynor. (*Id.* at ¶ 38.) On May 20, 2013, Kaspar emailed the Gaynors and wrote, “IND is coming along very well[.] Please find the audited draft report we are going thru,

⁶ NYS Department of State Division of Corporations Entity Information, https://appext20.dos.ny.gov/corp_public/CORPSEARCH.ENTITY_INFORMATION?p_token=E800FAC6A84978380709709F3416544D0D4B2B7686122E908785D5892E3E38823038DBCBB983A1BC810AF5E5BE685869&p_nameid=A6D5CD41B8167C1F&p_corpid=A6337A4B9D9035C6&p_captcha=12027&p_captcha_check=9E935A27FDD5EFE0&p_entity_name=sophias%20cure&p_name_type=A&p_search_type=BEGINS&p_srch_results_page=0 (last accessed Jan. 3, 2017) (emphasis added). This Court can take judicial notice of filings with the secretary of state. *See e.g., Malibu Media, LLC v. Steiner*, 307 F.R.D. 470, 474 (S.D. Ohio 2015) (“[T]he Court may take judicial notice of Plaintiff’s registration with the Ohio Secretary of State without converting Defendant’s motion into one for summary judgment.”)

right now 677 pages. Lots of work going on, but thought you would like to see our packet coming together.” (*Id.* at ¶ 55.)

On January 20, 2014, Kaspar sent John Carbona (former AveXis CEO) an email concerning scAAV9: “It will go down in history you me and Vinny [Gaynor] are the ones whom [m]ade this miracle happen.” (*Id.* at ¶ 72.) In response to Kaspar’s January 20 email, Carbona wrote, “I am driving you and Vinny to the party, I am on this train at a very late stage . . . [I]t[’]s all you guys!” (*Id.* at ¶ 73.) SCF *did* make this miracle happen by providing the NCH Entities with approximately \$1,800,000 and dedicating all of their time to finding a cure for SMA. (*Id.* at ¶ 74.)

Most notably, SCF possessed manufacturing data, which is typically in the Sponsor’s possession. *See id.* at ¶ 76 (“It is very important that AveXis be given access to certain manufacturing data that Reed would be more comfortable sharing with AveXis after a representative for Sophia’s Cure gave him written clearance.”); ¶ 77 (“Brian mentioned that you’ll need Sophia’s Cure’s permission to release formal documents to AveXis.”). As mentioned above, the House Report submitted in connection with the passage of the Orphan Drug Act explained, the *purpose of this seven-year market exclusivity period is to allow the orphan drug’s sponsor “to recoup the cost of development by capturing all revenues from the sale of the drug for the rare disease.”* H.R. REP. NO. 99–153, reprinted in 1985 U.S.C.C.A.N. 301, 303 (emphasis added). *See id.* at ¶ 87. Clearly, the seven-year exclusivity period was created to benefit a corporation like SCF.

SCF assumed the responsibility for both clinical and nonclinical investigation of scAAV9 should get the rights that it was promised.

The AveXis Defendants briefly mention in a footnote that the Grant Agreement provides that the Research Institute retain all ownership rights in the project. (Def’s Br. 10 n 10.) As fully addressed in SCF’s Memorandum in Opposition to the NCH’s Defendants Motion to Dismiss at pages 3 – 6, The Donation Agreement supersedes the preceding contract, the Grant Agreement.

B. The First Amended Complaint sufficiently alleges that the AveXis Defendants knew the terms of the Donation Agreement and intentionally procured such breach.

The AveXis Defendants contend that SCF fails to allege that the AveXis Defendants (1) had specific knowledge of any of the terms of the Donation Agreement and (2) procured any breach. (Def's Br. 11-15.) However, the FAC sufficiently alleges that the AveXis Defendants knew the terms of the Donation Agreement and intentionally procured such breach, (FAC ¶¶ 9, 67-71, 91-94, 101-04, 106, 124, 125.)

1. The AveXis Defendants knew the terms of the Donation Agreement and that their acts would interfere with the Donation Agreement.

The AveXis Defendants knew the terms of the Donation Agreement. (FAC ¶ 9, 67-71, 101-04, 106, 124.)

The AveXis Defendants contend that Kaspar's knowledge of the Donation Agreement and its terms cannot be imputed to AveXis because Kaspar did not receive the Donation Agreement in his capacity as an AveXis officer and SCF fails to allege that Kaspar received the Donation Agreement. (Def's Br. 12.) However, Kaspar's knowledge of the Donation Agreement and its terms can be imputed to AveXis and SCF alleges that Kaspar received a copy of the Donation Agreement.

Kaspar, AveXis's Chief Scientific Officer, Senior Vice President, Scientific Founder, and a Member of the Board of Directors, imputed his knowledge of the Donation Agreement, and its terms, to AveXis. (*Id.* at ¶ 67-71.)

The AveXis Defendants cite *Am. Mut. Share Ins. Corp. v. CUMIS Ins. Soc'y*, No. 08AP-576, 2009 WL 205373 (Ohio Ct. App. Jan. 29, 2009), but that case does not address the situation in our case. A case which dealt with a very similar situation is *Orrenmaa v. CTI Audio, Inc.*, 2008-Ohio-4299, ¶ 110 (Ohio Ct. App. 11th Dist. 2008).

“Ohio has long recognized ‘a corporation cannot see or know anything except by the eyes and intelligence of its officers.’” *Orrenmaa*, 2008-Ohio-4299, ¶ 110 (quoting *Orme v. Baker*, 74 Ohio St.

337, 78 N.E. 439 (Sup. Ct. Ohio 1906)). “A corporation can act only through its officer and agents, and *the knowledge of the officers of a corporation is at once the knowledge of the corporation.*” *Id.* (emphasis added). In *Orrenmaa*, Ousky learned of a building’s code violations and pending demolition in his capacity as President of Ominitronics. *Id.* at ¶ 106. Broad & Jackson was founded by Ousky and was formed after Ousyk learned of the building’s code violations and pending demolition. *Id.* at ¶ 108. The Court held that Ousky’s knowledge was imputed to Broad & Jackson. *Id.* at ¶ 111.

Similarly, Kaspar became aware of the Donation Agreement and its terms when he received a *copy* of the Donation Agreement on September 26, 2012. (FAC ¶ 47-48.)⁷ During this time, Kaspar was employed by the NCH Defendants and AveXis’s Chief Scientific Officer, Senior Vice President, Scientific Founder, and a Member of the Board of Directors. Kaspar’s knowledge of the Donation Agreement and its terms should be imputed to AveXis because similar to Ousky, Kaspar is a founder of the entity, AveXis, which purchased scAAV9. *See Orrenmaa*, 2008-Ohio-4299, ¶ 111.

The AveXis Defendants contend that the FAC supports their theory that AveXis did not know about the Donation Agreement or its terms. In addition to Kaspar’s knowledge being imputed to AveXis, the FAC also alleges that John Carbona (“Carbona”), the former CEO of AveXis, Sean Nolan (“Nolan”), current CEO of AveXis, and Arvind Sreedharan (“Sreedharan”), Vice President of AveXis, knew about the Donation Agreement and its terms. (FAC ¶ 9.)

The FAC is filled with examples supporting SCF’s allegation that Carbona knew about the Donation Agreement and its terms. *First*, on September 2, 2013, Carbona emailed Gaynor asking

⁷ The AveXis Defendants contend that the FAC only alleges that Kaspar was copied on an email but the email did not attach the Donation Agreement. This could not be further from the truth. Clearly, the FAC alleges, “On September 26, 2012, Arthur Scott, of the Foundation, emailed Vincent Gaynor, copying Timothy Robinson, the Treasurer/Officer on the Board of Directors for the Research Institute, the Foundation, and NCH, Kaspar, and Kevin Welch (“Welch”), NCH’s VP of Developmental Services, *a copy of the Donation Agreement.*” (FAC ¶ 47.) (emphasis added).

him to vote on the final design for “chariSMA.”⁸ (*Id.* at ¶ 64.) Carbona would not ask Gaynor to vote on the final design of the drug at issue in this case unless he believed SCF had sponsoring authority. *Second*, on October 2, 2013, Carbona emailed Gaynor, copying Minna Du, an employee at AveXis: “Would you do me a favor and work with Minna on developing some palliative care costs for treating a type 1 SMA patient?” (*Id.* at ¶ 65.) This is another example of Carbona asking Gaynor for his input with regards to scAAV9. *Third*, on January 20, 2014, Kaspar sent Carbona an email concerning scAAV9: “It will go down in history you me and Vinny [Gaynor] are the ones whom [m]ade this miracle happen.” (*Id.* at ¶ 72.) In response to Kaspar’s January 20 email, Carbona wrote, “I am driving you and Vinny to the party, I am on this train at a very late stage [I]t[?]s all you guys!” (*Id.* at ¶ 73.)

Fourth, although Carbona emailed Gaynor on July 30, 2014 asking for a copy of the Donation Agreement, Carbona knew of the Donation Agreement and its terms. On July 30, 2014, Carbona emailed Gaynor,

My concern is there are written provisions in those agreements that I am only vaguely familiar with, and as such, *AveXis may be bound in the future by those provisions* as the licensee. I would think I have a right to view them. One example is a provision that comes to mind is the *Recognition of SCF Role as the primary sponsor* of the trial [sic].

(*Id.* at ¶ 79.) (emphasis added). Carbona admits that he is familiar with the terms, that AveXis may be bound in the future by those terms, and that he knows there is a provision concerning the “*Recognition of SCF Role as the primary sponsor* of the trial [sic].” (*Id.*) (emphasis added).

Fifth, On February 24, 2014, Carbona sent an email to Vincent Gaynor acknowledging SCF as Sponsor and requesting manufacturing data (which is typically in the Sponsor’s possession):

Hello Vincent,

⁸ AveXis referred to scAAV9, the drug at issue in this case, as “chariSMA.” (FAC ¶ 63.)

Please take a look and review today[']s agenda between AveXis and NCH. Briefly the one part of the discussions pertained to Reed's Gold v Ector production and your *sponsoring* authority. I am sure most of the questions we had are shared by you as well. *It is very important that AveXis be given access to certain manufacturing data that Reed would be more comfortable sharing with AveXis after a representative for Sophia's Cure gave him written clearance. Would you drop Dr. Clark an email, letting him know its ok with you (Sophia's Cure) for RI to share the data with AveXis when requested. If you need to clear this Brian, please call him or reach out to Allan or Jayson to get further guidance.*

(*Id.* at ¶ 76.) (emphasis added). Carbona would not request that SCF release the manufacturing data to AveXis unless he thought SCF was the Primary Sponsor of scAAV9. *Sixth*, that same day, Kaspar's brother Allan Kaspar (VP of R&D at AveXis) emailed Kaspar a draft letter for Gaynor to send to Reed Clark (Associate Professor at NCH):

Dear Reed,

Brian gave me a quick update tonight, great news on the production release tests. He also told me that you are talking with AveXis about production-related issues. I am very happy to hear that and excited that you will be working with them. I met with their team last Friday and it sounds to me like they are ready and willing to carry the ball forward. *Brian mentioned that you'll need Sophia's Cure's permission to release formal documents to AveXis.* So, I'm happy to give that to you now: Please consider this email permission to release any and all manufacturing information that was supported by Sophia's Cure to AveXis. The support to get the manufacturing of the therapy to phase 1 must be carried forward, and I fully endorse the AveXis team to be working to carry out future manufacturing of the virus, not having to reinvent any of your efforts. It's been a team effort to get to this stage, and a bigger team will be needed to get to the phase 3. Thank you for your support. Let me know if you need additional formal documentation.

(*Id.* at ¶ 77.) (emphasis added). Again, AveXis and the NCH Defendants requested that SCF release manufacturing data, which is typically in the Sponsor's possession. Clearly, these facts alone establish that Carbona knew of the Donation Agreement and its terms because of Carbona's actions in dealing with Gaynor and SCF.

The FAC also alleges that Nolan, current CEO of AveXis, and Sreedharan, Vice President of AveXis, knew about the Donation Agreement and its terms. (FAC ¶ 9.) In addition to Kaspar and Carbona, Nolan and Sreedharan also knew about the Donation Agreement and its terms. On October 12, 2015, Gaynor told Nolan and Sreedharan, "We [SCF] have stipulations in our contract

that anytime there is a release of information, Sophia's Cure would be recognized as the Primary Sponsor. Now, I didn't do that for just trivial reasons, I knew that that the express voucher and according to the wording that if Sophia's Cure was notified as the Primary Sponsor, that belongs to us not AveXis." (FAC ¶ 101.)

Gaynor further clarified, "That's [Primary Sponsor] in my contract with Nationwide. So Nationwide didn't have the right to sell any of that to AveXis. I saw press releases that you guys [AveXis] own an express voucher. That's something that we are going to challenge." (*Id.* at ¶ 102.) This occurred prior to AveXis exercising its option in its license agreement with NCH permitting AveXis to become the Sponsor of the IND. (*Id.* at 106.)

2. The AveXis Defendants procured the breach of the Donation Agreement.

The AveXis Defendants intentionally procured the breach of the Donation Agreement. (FAC ¶¶ 9, 91-94, 106, 124, 125.)

"Intentional procurement" refers to conduct that causes the third party to breach the contract, or that leaves the third party with no choice but to breach the contract." *Union of Needletrades, Indus. & Textile Employees AFL-CIO v. Am. Capital Strategies, Ltd.*, 546 F. Supp. 2d 546, 560–61 (S.D. Ohio 2008) (quoting (Restatement § 766 cmt. h)). "Intentional" means that the actor must desire to cause a breach of contract, or know that breach of contract is substantially certain to result from the interference." *Id.* at 561. (quoting Restatement § 766 cmt. J).

The FAC alleges facts supporting the conclusion that the AveXis Defendants desired to cause the NCH Defendants to breach the Donation Agreement. On November 13, 2014, NCH conspired with AveXis and Kaspar to attempt to induce SCF into signing a Confidentiality and Non-Disclosure Agreement ("CDA") that would remove SCF as the Sponsor of scAAV9 and name AveXis the Sponsor. (FAC ¶ 91). Specifically, Stephen Testa (Vice President of Institutional Advancement at NCH) emailed the following to the Gaynors (copying Kaspar): "Please find the

attached agreements for your review: 1. Confidentiality and Non-Disclosure Agreement and 2. Gift Agreement for your review. The CDA is written as a 4-way agreement between Sophia's Cure, the Anonymous Donor, NCH, and AveXis. The gift agreement is between Sophia's Cure and Nationwide Children's Foundation.” (*Id.* at ¶ 92.) But, SCF refused to sign the CDA. (*Id.* at ¶ 94.) When SCF refused to sign the CDA which would remove SCF as the Sponsor of scAAV9 and name AveXis the Sponsor, AveXis decided to move forward and exercise its option in its license agreement with NCH permitting AveXis to become the Sponsor of the IND. (*Id.* at ¶ 106.)

Also, the FAC alleges facts supporting the conclusion that the AveXis Defendants knew that breach of the Donation Agreement was substantially certain to result from their interference. AveXis knew if they exercised their right in the license agreement with NCH, the NCH Defendants would be breaching the Donation Agreement. The FAC alleges that the AveXis Defendants knew the terms of the Donation Agreement, (FAC ¶ 9, 67-71, 101-04, 106, 124), and interfered with the terms of the Donation Agreement. (FAC ¶ 125-26.)

C. The First Amended Complaint sufficiently alleges that the AveXis Defendants' actions were unjustified.

The AveXis Defendants lacked justification in entering into the license agreement with NCH because the AveXis Defendants knew the Donation Agreement named SCF the Primary Sponsor prior to executing the license agreement. (FAC ¶¶ 67-71.)

“[I]n determining whether an actor has acted improperly in intentionally interfering with a contract consideration should be given to the following factors: [1] the nature of the actor's conduct, [2] the actor's motive, [3] the interests of the other with which the actor's conduct interferes, [4] the interests sought to be advanced by the actor, [5] the social interests in protecting the freedom of action of the actor and the contractual interests of the other, [6] the proximity or remoteness of the actor's conduct to the interference, and [7] the relations between the parties.” *Union of Needletrades*,

546 F. Supp. 2d at 561 (S.D. Ohio 2008) (quoting *Fred Siegel Co., L.P.A. v. Arter & Hadden*, 85 Ohio St.3d 171, 178-79, 707 N.E.2d 853 (Sup. Ct. Ohio 1999)).

The AveXis Defendants cite *M.J. McPherson Servs., L.L.P. v. Sports Images, Inc.*, No. 5:06 CV 465, 2006 WL 2505925, at *4 (N.D. Ohio Aug. 28, 2006). (Def's Br. 16.) However, the facts in *M.J. McPherson*, are inapposite to the facts in this case. In *M.J. McPherson*, the Court held that the Complaint failed to set forth facts demonstrating defendant acted improperly because the Complaint did not assert the existence of a trade secret and that defendant improperly made use of plaintiff's customer list. *Id.* at *4.

In contrast, the FAC alleges facts sufficiently establishing the seven factors. *First*, the FAC alleges that although AveXis knew about the Donation Agreement and its terms, the AveXis Defendants still executed the licensing agreement and later exercised its option to become the Sponsor of the IND. (FAC ¶ 9, 67, 106.) *Second*, the AveXis Defendants' motive was to interfere with the Donation Agreement so that AveXis could become the Primary Sponsor of the IND and have the exclusive right to market scAAV9 for seven years. (*Id.* at ¶ 9, 89, 106.) *Third*, SCF has an interest in the IND because the Donation Agreement names SCF the Primary Sponsor. SCF provided the financial support and time to develop scAAV9. (*Id.* at ¶ 33, 74.) *Fourth*, the AveXis Defendants sought to financially benefit from the Primary Sponsor designation at the cost of SCF. (*Id.* at ¶ 1, 106.) *Fifth*, social interests do not protect the AveXis Defendants' greed in taking advantage of SCF and cutting them out of the benefits of the Primary Sponsor designation. (*Id.* at ¶ 106.)

Sixth, the AveXis Defendants' conduct was very close in time to the interference with the Donation Agreement. When SCF refused to sign the CDA which would remove SCF as the Sponsor of scAAV9 and name AveXis the Sponsor, AveXis decided to move forward and exercise its option in its license agreement with NCH permitting AveXis to become the Sponsor of the IND.

(*Id.* at ¶ 106.) *Seventh*, the AveXis Defendants had significant influence on the NCH Defendants. For example, Kaspar had a major role in the Donation Agreement and is also a Founder, Chief Scientific Officer, Senior Vice President, and a Member of the Board of Directors at AveXis. (*Id.* 16.)

Therefore, the AveXis Defendants lacked justification in entering into the license agreement and exercising its option in the license agreement to become the Sponsor of the IND.

CONCLUSION

For the reasons stated above, the Court should deny the AveXis Defendants' motion to dismiss.

Dated: March 20, 2017

Respectfully submitted,

By: /s/ John R. Climaco
John R. Climaco (0011456)
Climaco, Wilcox, Peca, Tarantino &
Garofoli
55 Public Square
Suite 1950
Cleveland, Ohio 44113
Toll Free: (800) 621-1062
Phone: (216) 621-8484
Fax: (216) 771-1632
jrclim@climacolaw.com

Patrick G. Warner (0064604)
Darrin C. Leist (0070533)
Leist Warner LLC
513 East Rich Street, Suite 201
Columbus, Ohio 43215
Telephone: (614) 222.1000
Facsimile: (614) 222-0890
pwarner@leistwarner.com

Salvatore C. Badala (*pro hac vice*)
NAPOLI SHKOLNIK PLLC
360 Lexington Avenue, 11th Floor
New York, New York 10017
Tel: (212) 397-1000
Fax: (646) 843-7603
Email: sbadala@napolilaw.com

Counsel for Plaintiff

CERTIFICATE OF SERVICE

I, Salvatore C. Badala, an attorney, hereby certify that on March 20, 2017, I electronically filed the foregoing memorandum of law in opposition to the AveXis Defendants' motion to dismiss with the Clerk of the Court for the Southern District of Ohio by using the CM/ECF System which will send notification of such filing to all counsel of record in this action.

/s/ Salvatore C. Badala

Salvatore C. Badala (*pro hac vice*)
NAPOLI SHKOLNIK PLLC
360 Lexington Avenue, 11th Floor
New York, New York 10017
Tel: (212) 397-1000
Fax: (646) 843-7603
Email: sbadala@napolilaw.com

Counsel for Plaintiff